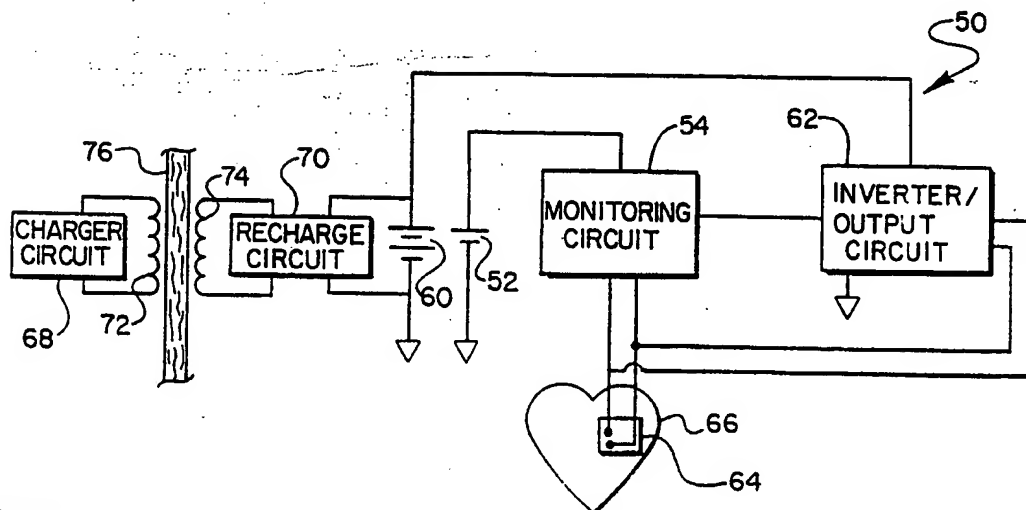




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(54) Title: DUAL BATTERY SYSTEM FOR IMPLANTABLE CARDIOVERTER DEFIBRILLATOR**(57) Abstract**

An improved dual battery power system uses two separate battery power sources for an implantable cardioverter defibrillator, each having optimized characteristics for monitoring functions and for output energy delivery functions, respectively. The monitoring functions are supplied electrical power by a first battery source, such as a conventional pacemaker power source in the form of a pair of lithium iodide batteries, which is optimized for long life at very low current levels. The output energy delivery functions are supplied by a separate second battery source, such as a pair of lithium vanadium pentoxide batteries, which is optimized for high current drain capability and low self-discharge for long shelf life. The first battery source provides electrical power only to the monitoring functions of the implantable cardioverter defibrillator, and the second battery source provides all of the electrical power for the output energy delivery functions.

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DUAL BATTERY SYSTEM FOR IMPLANTABLE CARDIOVERTER
DEFIBRILLATOR

BACKGROUND OF THE INVENTION

1. Field of the Invention - The present invention pertains to a
15 cardioverter defibrillator, and more particularly, to an improved dual
battery power system for use with an implantable cardioverter
defibrillator.

2. Background of the Invention - Implantable cardioverter
defibrillators have several unique battery requirements, as compared to
20 other implantable products. An implantable cardioverter defibrillator
demands a battery with the following general characteristics: very high
reliability, highest possible energy density (i.e., small size), extremely low
self-discharge rating (i.e., long shelf life), very high current capability, high
operating voltage, and high sealability (i.e., no gas or liquid venting).

25 Some of these parameters have some measure of mutual
exclusivity, making it difficult to optimize the battery or electronics
without making compromises to the design of the implantable device. In
its monitoring mode, the implantable cardioverter defibrillator requires
the battery to deliver continuous currents in the range of only 10 - 30 μ A,
30 while in its defibrillation mode, the same battery must deliver currents in
the range of one to two amps, some five orders of magnitude greater than
the current required for the monitoring mode.

Presently, all manufactured implantable cardioverter defibrillators use a single battery system to power the implantable device. The longevity of an implanted cardioverter defibrillator with a single battery configuration and the number of shocks the defibrillator is capable of delivering are strictly dependant on the remaining battery capacity at any given time. As the device ages, its ability to deliver an adequate number of defibrillating shocks declines as the battery is depleted by the monitoring electronics. Similarly, if a patient receives a large number of shocks soon after implant, the remaining monitoring life is reduced. Thus, it is difficult to assess the condition of the battery and its remaining useful life after it has been in use for a period of time.

A further disadvantage of the single battery configuration is that the ideal voltage requirements for the monitoring and output functions are opposite. For the monitoring function, it is desirable to use the lowest possible voltage that the circuits can operate reliably with in order to conserve energy. This is typically in the order of 1.5 - 3.0 V. On the other hand, the output circuit works most efficiently with the highest possible battery voltage in order to produce firing voltages of up to about 750 V.

All existing manufactured implantable cardioverter defibrillators have compromised between these two demands by using a single battery system or configuration which is typically comprised of two lithium silver vanadium pentoxide cells electrically connected in series to produce an output battery voltage of about 6 V. The battery voltage must be elevated via an inverter circuit to the firing voltage of about 750 V. The net result is that power is wasted in both the monitoring and output circuits because the monitoring circuit which requires only 2-3 V must operate from a relatively high 6 V source, and the output circuit whose efficiency is a function of the supply voltage must operate from the relatively low 6 V source.

At least two previous development attempts have been made to avoid some of the problems inherent in using a single battery system configuration for an implantable cardioverter defibrillator. In the

Medtronic Model 2315, lithium thionyl chloride batteries were employed for the high-voltage charging circuit and lithium manganese dioxide batteries were used for the remaining low voltage circuitry. Similarly, the Teletronics Model 4201 initially tried to employ separate batteries for the low voltage circuits (lithium iodine) and high-voltage circuits (lithium silver vanadium pentoxide). Troop, P.J., "Implantable Cardioverters and Defibrillators", Current Problems in Cardiology, Vol. XIV, No. 12, (Dec. 1989), pp. 703-04. Unfortunately, neither of these devices resulted in practical, manufactured implantable cardioverter defibrillators and the dual battery approach was abandoned in both cases.

While single battery systems have proved workable for implantable cardioverter defibrillators, the use of a single battery system necessarily involves a compromise between the ideal power supplies which would otherwise be used for the various types of circuitry within the implantable cardioverter defibrillator. Accordingly, it would be desirable to provide for an improved dual battery power system for an implantable cardioverter defibrillator which avoids the need for the compromises required of single battery systems, and which overcomes the problems of earlier attempts at dual battery systems.

SUMMARY OF THE INVENTION

An improved dual battery power system in accordance with the present invention involves the use of two separate battery power sources for an implantable cardioverter defibrillator, each having optimized characteristics for monitoring functions and for output energy delivery functions, respectively. The monitoring functions are supplied electrical power by a first battery source, such as a conventional pacemaker power source in the form of a pair of lithium iodide battery cells, which is optimized for long life at very low current levels. The output energy delivery functions are supplied by a separate second battery source, such as a pair of lithium vanadium pentoxide battery cells, which is optimized for high current drain capability and low self-discharge for long shelf life. The

first battery source provides electrical power only to the monitoring functions of the implantable cardioverter defibrillator, and the second battery source provides all of the electrical power for the output energy delivery functions.

5 With the improved dual battery system configuration of the present invention, the minimum expected monitoring life of an implantable cardioverter defibrillator is independent of the amount of electrical pulse therapy delivered by the device, such as the number of cardioversion/defibrillation countershocks or the amount of pacing. As a result, the end
10 of the minimum useable lifespan of the first battery source is highly predictable based on steady state current drain calculations. The lifespan of the second source battery source is also amenable to calculation based upon the number and amount of energy levels of previously delivered electrical pulse therapies.

15 The major advantage of the present invention is that each battery source voltage can be optimized for the particular circuit wherein it is used. The first battery source is preferably a relatively low current, low voltage source, from 1.5 to 3.0 V typically; whereas the second battery source is preferably comprised of as high of a current and voltage as battery
20 chemistry and battery packaging efficiencies allow, typically ranging from 6 to 18 V.

 Unlike existing implantable cardioverter defibrillators, a preferred embodiment of the present invention utilizes a separate hardware-based, low-power monitoring circuitry to monitor for certain wake-up conditions
25 which will then activate the output delivery circuitry which includes a microprocessor that performs further detection and, if necessary, selects an appropriate cardioversion/defibrillation therapy to be delivered. The output delivery circuitry includes additional hardware circuitry that, when enabled, can delivery pacing therapy pulses with energy supplied from the
30 output power source battery without the need to wake the microprocessor.

 Because the two batteries of the present invention can be optimized for their particular functions, different assumptions about the total energy

requirements of the implantable cardioverter defibrillator can be made. For example, all existing manufactured implantable cardioverter defibrillators provide power systems which are designed to supply an initial number of defibrillation countershocks of at least 250 shocks. In a
5 single battery system, even when no shocks are delivered, the number of remaining shocks in the device decreases with age due to the fact that the energy for the monitoring functions are drawn from this battery. In the present invention, assuming good charge retention of the output battery, essentially no energy is drawn from the output battery until an electrical
10 pulse therapy is delivered. Consequentially, one advantage of the dual battery system of the present invention is that a smaller initial number of defibrillation countershocks is required to maintain the same minimum expected life span for the device, thereby allowing a reduction in the overall size of the implanted device.

15 Another advantage of a preferred embodiment of the present invention includes a backup protection feature whereby energy from the output power source battery can be used to power the monitoring circuitry in the event that the monitoring power source battery ceases to function. Still other advantages include a greater longevity provided for by lower
20 energy drain by the monitoring circuitry, the simplified circuit design that results in a decrease in the risk of high internal currents causing interference to other parts of the low current monitoring and control circuitry, and the ability to use rechargeable batteries.

25 BRIEF DESCRIPTION OF THE DRAWING

FIG. 1 illustrates a block diagram of a single battery system for an implantable cardioverter defibrillator;

FIG. 2 illustrates a block diagram of the dual battery system of the present invention for an implantable cardioverter defibrillator;

30 FIG. 3 illustrates a block diagram of the dual battery system of the present invention using a rechargeable inserter/output battery;

FIGS. 4a, 4b, 4c, 4d and 4e are graphs comparing the predicted lifespan of an implantable cardioverter defibrillator having a single battery system and a dual battery power system; and

FIGS. 5a and 5b is a schematic diagram of a preferred embodiment of
5 the present invention.

FIG. 6 is a detailed schematic diagram of the backup feature of the embodiment of the present invention shown in FIGs. 5a and 5b.

DESCRIPTION OF THE PREFERRED EMBODIMENT

10 FIG. 1 illustrates a single battery system for an implantable defibrillator system 10 including a single battery 12, which provides power both to a monitoring circuit 14 and an inverter/output circuit 16 simultaneously. The monitoring circuit 14 and the inverter/output circuit 16 are interconnected to each other, and to two or more implanted
15 electrodes 18 located on, near or in a heart 20. The implanted electrodes 18 include appropriate leads and sensors to monitor the electrical activity of the heart 20 and to deliver an appropriate electrical therapy to the heart 20 in the event that the monitoring circuit detects a cardiac arrhythmia. As discussed in the background of the invention, the electrical size of the
20 single battery 12 may be excessive in relation to the circuit requirements of the monitoring circuit 14, and marginal or even somewhat lacking in electrical size in relation to the circuit requirements of the inverter/output circuit 16.

FIG. 2 illustrates a block diagram of the dual battery system 30 for an
25 implantable defibrillator of a preferred embodiment of the present invention. A battery 32 of appropriate voltage and physical size connects to and powers a monitoring circuit 34 only. Another battery 36 of appropriate voltage and physical size connects to and powers the inverter/output circuit 38 only. The monitoring circuit 34 and the
30 inverter/output circuit 38 each connect to two or more implanted electrodes 40 on, near or in a heart 42. The monitoring circuit 34 also connects to and triggers the inverter/output circuit 38. The batteries 32

and 36 are optimally sized electrically and physically to provide for the most efficient operation for their respective circuitry.

FIG. 3 illustrates a dual battery system 50 for an implantable defibrillator of an alternate embodiment of the present invention where the batteries are rechargeable. A battery 52 of appropriate voltage and physical size connects to and powers a monitoring circuit 54 only. Another battery 60, which is rechargeable and of appropriate voltage and physical size connects to and powers the inverter/output circuit 62 only. Charging of the battery 60 occurs by a radio frequency inductive link between an external charger circuit 68 and an implanted recharge circuit 70. A coil 72 connects with the external charger circuit 68 and transmits RF energy from the coil 72 through the epidermis 76 where it is received by an implanted coil 74. The coil 74 supplies RF energy to the recharge circuit 70 so that the battery 60 may be charged.

In operation, as in FIG. 2, the monitoring circuit 54 and the inverter/output circuit 62 each connect to two or more implanted electrodes 64 on, in or near a heart 66. The monitoring circuit 54 also connects to and triggers the inverter/output circuit 62. The batteries 52 and 60 are optionally sized electrically and physically to provide for the most efficient operation. In this configuration, the device has a finite and predictable monitoring life based upon the capacity of the primary monitoring battery 52, and an infinite life for the output power surface battery 60 based on a theoretically perfect secondary rechargeable battery that only needed to be recharged after a predetermined number of electrical pulse therapies were delivered. Optionally, the battery 52 which powers the monitoring circuit 54 can also be rechargeable and would also include another similar RF inductive charging link as used for the rechargeable battery 60.

A preferred mode of operation of the implantable cardioverter defibrillator shown in FIG. 2 is dependent upon the monitoring circuit 34 and the inverter/output circuit 38. In the event that the monitoring circuit 34 detects a wake-up condition, for example, the monitoring circuit

34 wakes up a microprocessor-based circuit in the inverter/output circuit 38 to respond to the wake-up condition. In the event that the monitoring circuit 34 is programmably enabled for pacing detection, and the monitoring circuit 34 detects a pacing condition, the monitoring circuit 5 enables a hardware-based pacing circuit portion of the inverter/output circuit 38 to deliver a pacing pulse using energy from the battery 36. It will be noted that many different variations in conditions detected by the monitoring circuit 34 and types of responses provided by the inverter/output circuit 38 are possible, and it is intended that such 10 combinations are within the scope of the present invention.

In one embodiment, a microprocessor with an RC gated oscillator circuit that is controlled by the microprocessor within the inverter/output circuit 38 implements a wake-up control that can respond to the wake-up conditions. The wake-up conditions handled by the microprocessor based 15 circuit in the inverter/output circuit 38 include, for example, a tachycardia threshold determination, a telemetry indication, or a timer condition. In the case of the tachycardia threshold determination, for example, threshold determination circuitry in the monitoring circuit 34 detects the occurrence of 3 consecutive R-waves at a rate faster than a predetermined 20 programmable rate. In response, the monitoring circuit 34 wakes-up the microprocessor in the inverter/output circuit 38, which verifies that a cardiac arrhythmia is occurring and selects an appropriate electrical pulse therapy. If an electrical pulse therapy is to be delivered, the battery 36 would charge the inverter/output circuit 38 to deliver one or more high 25 voltage cardioversion/defibrillation countershocks. If the wake-up condition was a telemetry indication, then the microprocessor circuit of the inverter/output circuit 38 might "output" a telemetry response, for example, rather than a electrical pulse therapy response. Alternatively, if the microprocessor circuit of the inverter/output circuit 38 determines 30 that no action is required in response to the wake-up condition, then no "output" may be generated in response and the microprocessor would

turn off the RC gated oscillator circuit, thereby shutting off the clock to the microprocessor.

One important feature which distinguishes the improved dual battery system 30 from the previous attempts to implement dual battery systems is that the division of labor between the battery 32 and the battery 36 is not based on low voltage output vs. high voltage output, but rather is based on monitoring functions vs. output functions. In the two dual battery systems described in the background art section, all of the low voltage circuitry of the implantable cardioverter defibrillator was powered from a low voltage battery. As a result, both the monitoring function (which typically operate on 3 V levels), as well as the pacing therapy output functions (which typically operate on 6 V levels), were designed to derive their energy from the low voltage battery. The end result of this type of arrangement is that the life of the low voltage battery is totally dependant upon the amount of pacing therapy which may be delivered by the device and, thus, the minimum effective life of the device is effectively unknown.

In contrast, the improved dual battery power system of the present invention takes all of its "output" energy from the output battery 32. For example, the present invention does not take the energy for pacing therapy from the monitoring battery 32, but rather from the output battery 36. As a result, the monitoring lifespan of an implantable defibrillator in accordance with the present invention is known and calculable based on the specifications of the monitoring battery 32. Without a known lifespan of the device, it is simply not possible to provide a viable implantable defibrillator, as evidenced by the fact that both of the previous attempts at dual battery systems which did not have known lifespans for the monitoring circuitry were unsuccessful and did not result in manufactured implantable cardioverter defibrillators.

Referring now to FIGs. 4a-4e, a comparison between the electrical pulse therapy outputs and the longevity of the implantable cardioverter defibrillator is shown under various assumptions for a single battery

system 100 and the improved dual battery system 102 of the present invention. One of the advantages of the present invention is that a smaller initial number of countershocks is required in order for the implantable cardioverter defibrillator to have the same minimum effective life span as a device with a single battery power system. This, in turn, decreases the overall power requirements, and, hence, the total size of the implantable cardioverter defibrillator. In the preferred embodiment, an additional advantage of having a more optimum discharge capacitor system in the implantable cardioverter defibrillator of a preferred embodiment also reduces the overall power requirements for the dual battery system of the present invention. For a more detailed explanation of the relationship between the therapies provided by the device and the power requirements and size of the device in the preferred embodiment, reference is made to PCT/US93/03249.

In FIG. 4a, the graph shows a comparison of the devices under an assumption that the device will deliver five maximum defibrillation countershock pulses per month and that pacing is not enabled. It will be noted that in a preferred embodiment of the present invention, the initial number of shocks is 150, as compared with 275 for the other device. It will also be noted, however, that the expected minimum life span of both the single battery system 100 and the present invention 102 are equal at 30 months under these assumptions.

In FIG. 4b, the graph shows a comparison of the devices under an assumption that the device will deliver one defibrillation countershock pulse per month and that pacing is not enabled. In this example, the dual battery system 102 of the present invention has more remaining shocks after 30 months than the single battery system, even though it started with almost one-half the initial number of shocks.

In FIG. 4c, the graph shows a comparison of the devices under an assumption that the device will deliver no defibrillation countershock pulses and that pacing is not enabled. Again, due to the energy drain on the single battery system 100 associated with its monitoring functions, the

1 dual battery system 102 of the present invention provides a longer life
2 span with more average remaining shocks available over that life span.
3 This graph also shows how the energy of the output battery remains
4 relatively the same (i.e., same number of remaining shocks) when no
5 output therapies are delivered.

In FIG. 4d, the graph shows a comparison of the devices under an assumption that the device will deliver one defibrillation countershock pulse per month and that pacing is enabled and will be utilized 50% of the time. Again, the dual battery system 102 of the present invention has a longer life span and more average remaining shocks over that life span. It is interesting to note that this situation, the previous dual battery systems described in the background art section would encounter a severe problem. After a period of 50% pacing, all of the energy from the low voltage battery would have been drained, and the device would abruptly
15 stops working, even though there were plenty of shocks remaining in the high voltage battery. It is speculated that this is one of the major reasons why implantable cardioverter defibrillators using the previous dual battery systems were never manufactured.

In FIG. 4e, the graph shows a comparison of the devices under an assumption that the device will deliver no defibrillation countershock pulses and that pacing is enabled and will be utilized 50% of the time. Once again the dual battery system 102 of the present invention has a longer life span and more average remaining shocks over that life span. As with the problem of the previous dual battery systems described with respect to FIG. 4d, such an end-of-monitoring life problem is even more pronounced in this situation as essentially all of the initial energy of the high voltage battery remains unused in the previous dual battery systems, but the device is "dead" because the low voltage battery is drained of its energy due to the energy requirements of the pacing therapy outputs.

30 Referring now to FIGs. 5a and 5b, a more detailed explanation of a preferred embodiment of the dual battery power system of the present invention will be described.

A pair of LiI monitoring battery cells 111, 112 provide a low current, low voltage output of about 2.0 - 2.8 V with a maximum current draw on the order of 10 μ Amps. The output of the monitoring battery cells 111, 112 is capacitively decoupled by a capacitor 114. Schottky diodes 118 and 120
5 enable the power system to run the 3 V bus from the battery cells 111, 112 during battery startup sequencing such that the device can be successfully initiated by first inserting the pair of battery cells 111, 112 before the output batteries are inserted.

A pair of LiAgV₂O₅ output battery cells 121, 122 provide a relatively
10 high current, high voltage output of 4.0 to 6.5 V with a maximum current draw of between about 2.0 - 4.0 A. The high current output of the output battery cells 121, 122 is capacitively decoupled by a capacitor 124. A center point ground 126 isolates the high current portion of the circuitry from the low current portion of the circuitry, thereby allowing for simpler circuit
15 design and greater reliability of the low current portion of the circuitry. A voltage booster 130 insures a 6 V supply on the 6 Volt Bus, while the diode 132 in the voltage booster 130 isolates the boosted voltage from the battery cell voltage during periods of high current draw.

An inverter circuit 140 uses the high current output and an
20 Inverter Gate Drive Voltage of 12 to 18 volts provided by a 3X charge pump circuit 142 from the 6 Volt Bus to drive a high-voltage flyback transformer in the inverter circuit 140. The output of the transformer charges a capacitor system (not shown) to produce the high voltage (50-800 V) capacitive discharge output pulse which forms either a cardioversion
25 or defibrillation pulse countershock. The Inverter Gate Drive Voltage is capacitively decoupled by capacitor 144.

The Main System Power is a regulated 3.0 V supplied primarily by the monitoring battery cells 111, 112, unless the current draw on the Main System Power exceeds about 10 μ A. In the event of a current overdraw
30 situation, such as when the microprocessor in inverter/output circuitry 38 responds to a wake-up condition, the output of the output battery cells 121, 122 is added to the output of the monitoring battery cells 111, 112 to

generate the required current. The circuitry to accomplish this is shown generally at 150 and is described in greater detail in connection with the description of FIG. 6.

The unregulated 2.5 V output of the monitoring battery cells 111, 5 112 is supplied as an input to a 3/2 charge pump 136 which, like the 3X charge pump circuit 142, is driven by a 1 KHz output of a 32 KHz oscillator crystal 134. The charge pump circuit 136 raises the output of the monitoring batteries to about 3.75 V which is capacitively decoupled by capacitor 146. The 3.75 V output of the charge pump circuit 136 and the 10 unregulated 6.0 Volt Bus are fed as inputs to a dual input voltage regulator 152. A voltage/current reference circuit 146 provides a reference voltage of 1.28 V and a reference current of 100 nA to the voltage regulator 152. A p-n-p transistor 154 controls whether the 6.0 Volt Bus input will be added to the 3.75 V output of the charge pump circuit 136 if a current overdraw 15 condition exists with respect to the monitoring battery cells 111, 112. The charge pump circuit 136 also provides a negative output of -2.0 to -2.5 V to supply the Main Power System negative voltage requirements for op amps, etc.

Referring now to FIG. 6, a more detailed explanation of the 20 operation of the backup feature of a preferred embodiment of the present invention is shown. A feedback amplifier circuit 156 compares the reference voltage signal from the voltage/current reference circuit 146 to a divided down value of the 3 Volt Bus signal. The divide down is accomplished by resistors 158 and 160 and capacitor 162. A FET transistor 25 circuit 164 responds to an output of the feedback amplifier circuit 156 to keep the voltage on the 3 Volt Bus at 3.0 V. If the current drain through the gate of the FET transistor circuit 164 is more than the maximum current draw for the monitoring battery cells 111, 112, then the transistor circuit 154 is turned on by feedback amplifier circuit 156 to supply the 30 necessary overdraw current from the output battery cells 121, 122 via the 6 Volt Bus.

WE CLAIM:

CLAIMS

- 1 1. An improved power system for an implantable cardioverter
2 defibrillator that is a self-contained human implantable device having
3 monitoring means for detecting myocardial arrhythmias in a human
4 patient and output means for selectively determining an appropriate
5 electrical pulse therapy to be delivered in response to a myocardial
6 arrhythmia detected by the monitoring means and delivering the
7 appropriate electrical pulse therapy to two or more implanted electrodes,
8 the improved power system comprising:
9 first battery means for providing electrical power primarily
10 only to the monitoring means; and
11 second battery means for providing substantially all of the
12 electrical power to the output means,
13 such that a minimum expected lifespan of the first battery
14 means is predictable regardless of the electrical pulse therapies
15 delivered by the implantable cardioverter defibrillator.
- 1 2. The improved power system of claim 1 wherein the output means
2 selects the appropriate electrical pulse therapy from a set that includes:
3 one or more cardioversion/defibrillation pulses, each
4 cardioversion/defibrillation pulse being delivered by the output
5 means as a capacitive discharge pulse from a capacitor means for
6 storing an electrical charge which is charged from the second battery
7 means; and
8 one or more pacing pulses, each pulse being delivered by the
9 output means as an electrical pulse directly powered from the
10 second battery means.

- 1 3. The improved power system of claim 1 further including:
2 backup means for allowing the second battery means to
3 provide electrical power to the monitoring means in the event that
4 the first battery means can no longer provide electrical power to the
5 monitoring means.
- 1 4. The improved power system of claim 3 wherein the backup means
2 comprises:
3 transistor means operably connected to outputs of the first
4 battery means and the second battery means to sense a current drain
5 on the output of the first battery means and switch on the output of
6 the second battery means to add to the output of the first battery
7 means in the event that the current drain exceeds a maximum
8 current drain of the first battery means.
- 1 5. The improved power system of claim 1 further including:
2 voltage regulation means operably connected to an output of
3 the first battery means and to a reference voltage value for
4 regulating the output of the first battery means to a predetermined
5 voltage value.
- 1 6. The improved power system of claim 1 wherein the first battery
2 means is a relatively low current source, and wherein the second battery
3 means is a relatively high current source.
- 1 7. The improved power system of claim 4 wherein the relatively low
2 current source is a 1.5 to 3.0 volt battery and the relatively high current
3 source is a 6 to 18 volt battery.
- 1 8. The improved power system of claim 1 wherein the first battery
2 means is two or more lithium iodide battery cells.

- 1 9. The improved power system of claim 1 wherein said second battery
2 means is two or more battery cells selected from the group consisting of:
3 lithium silver vanadium oxides, thionyl chlorides or
4 rechargeable battery cells.

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Fig.1

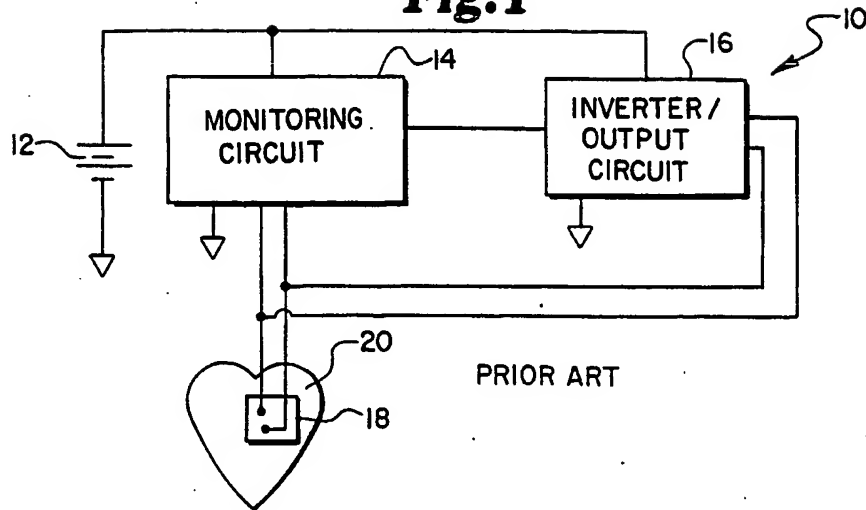


Fig.2

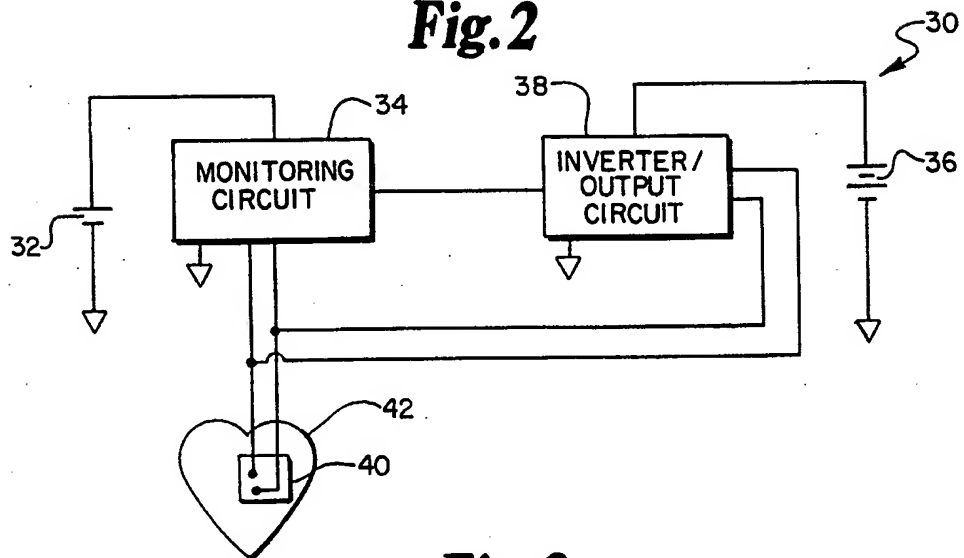
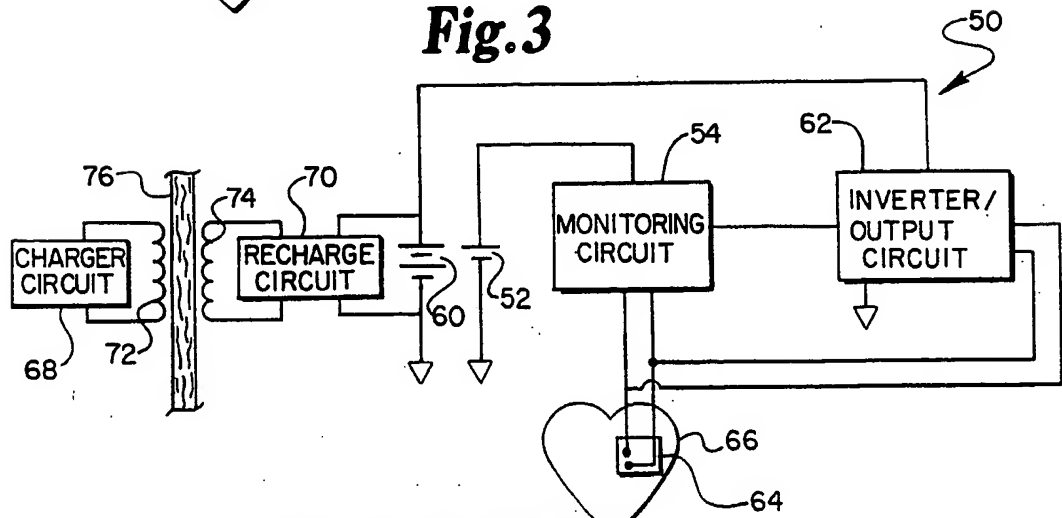
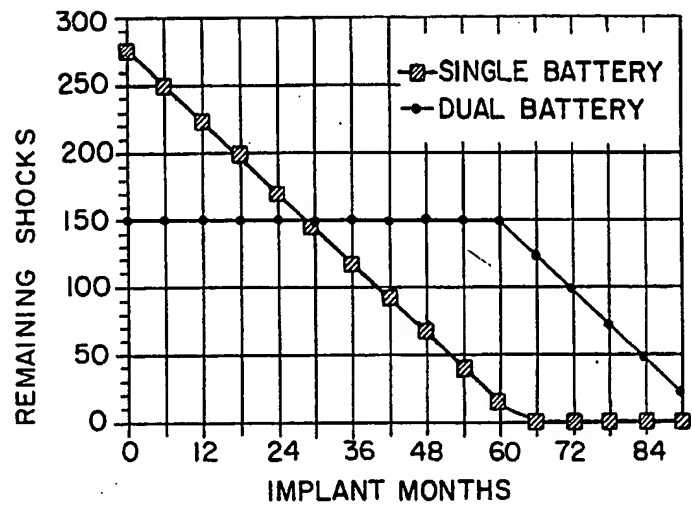
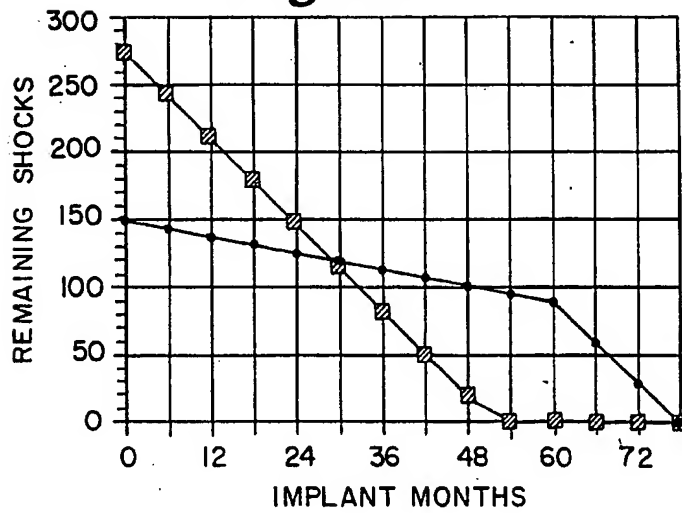


Fig.3

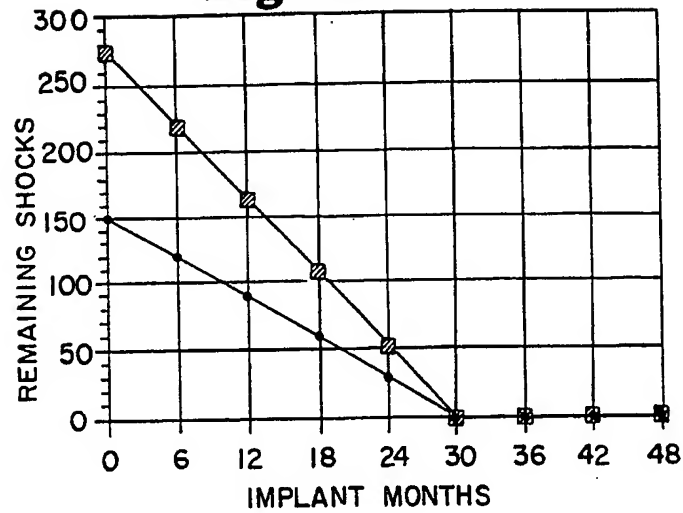
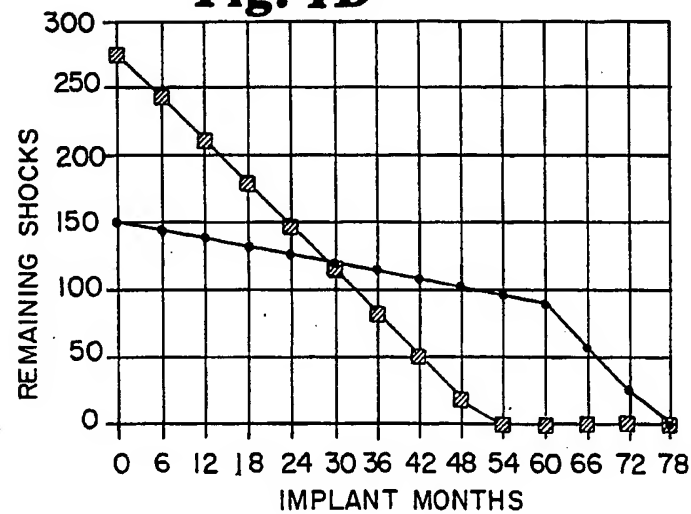
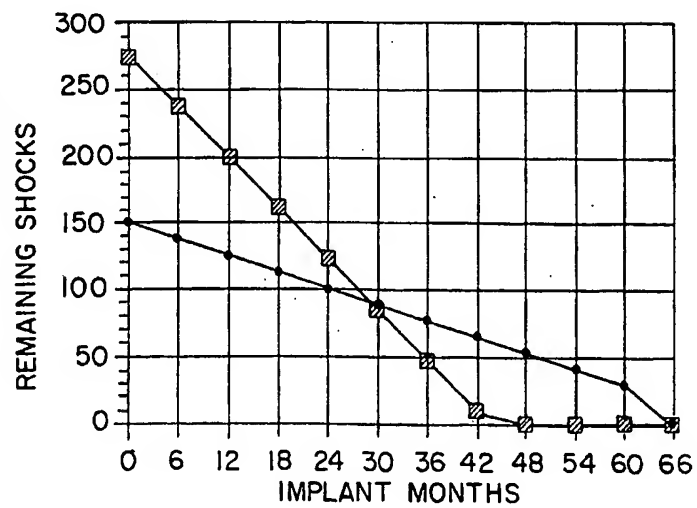


SUBSTITUTE SHEET

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Fig. 4A**Fig. 4B**

3/6

Fig. 4C**Fig. 4D****Fig. 4E**

SUBSTITUTE SHEET

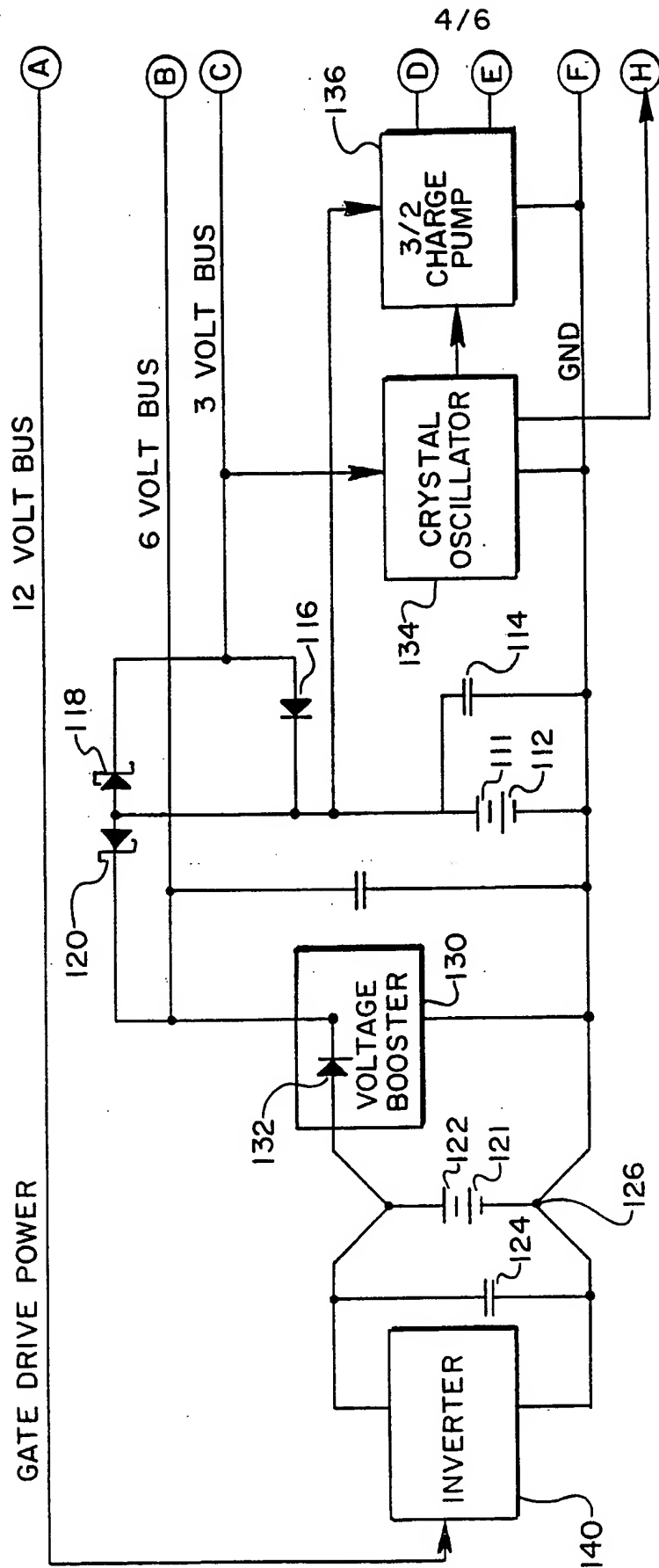


Fig. 5a

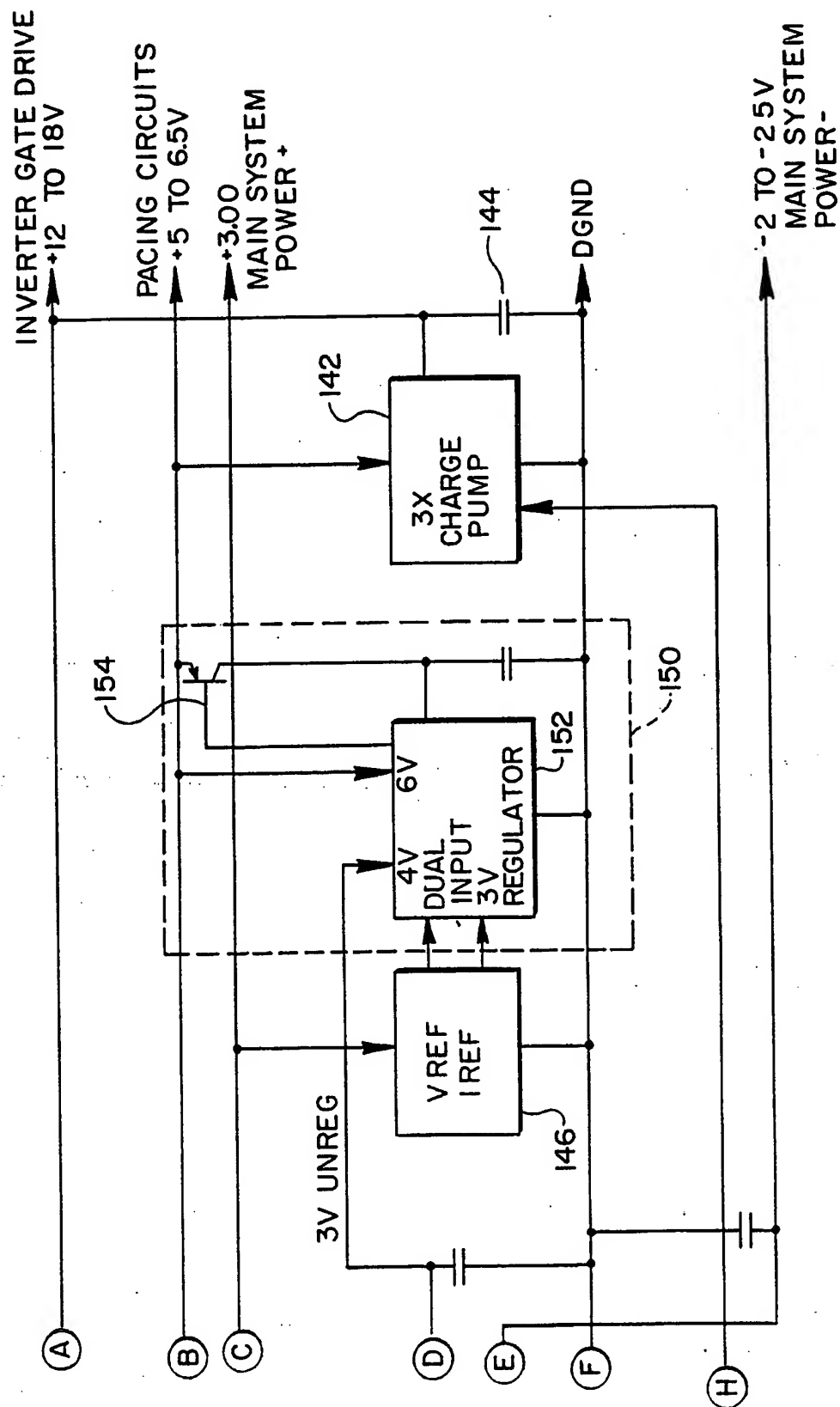
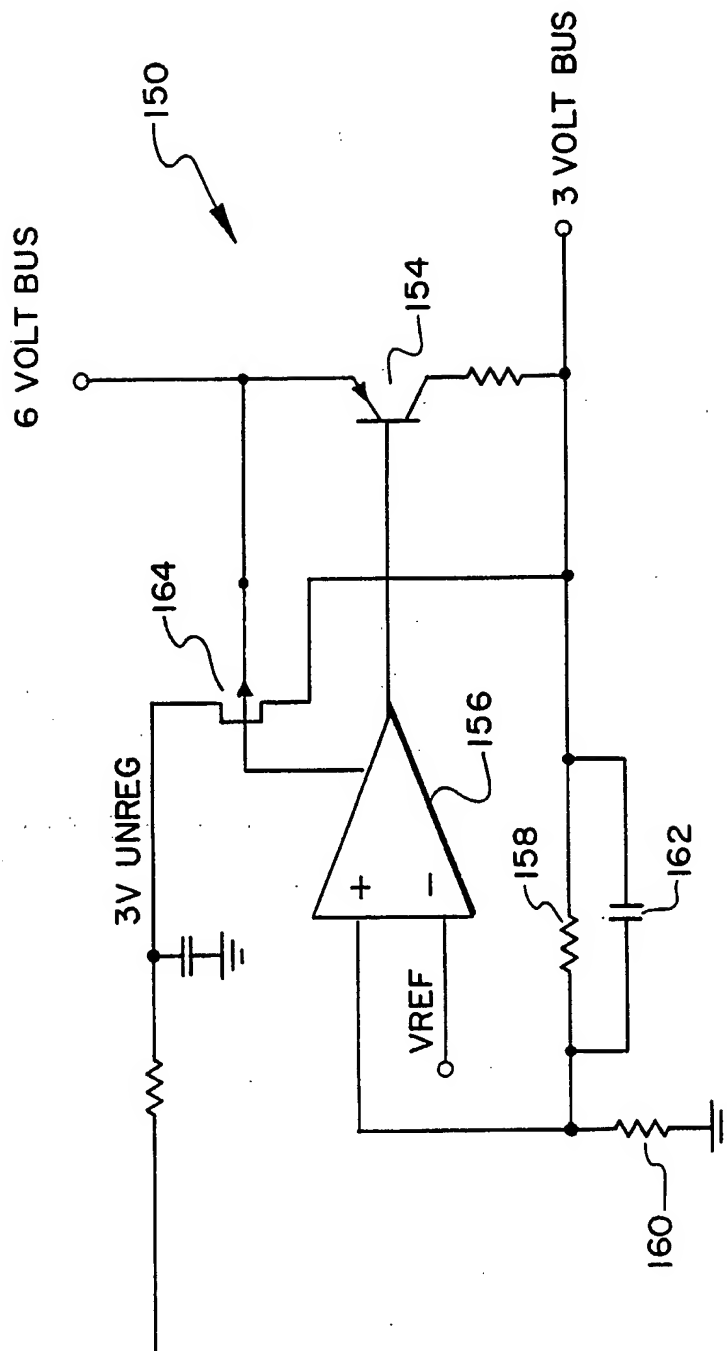


Fig. 5b

Fig. 6



INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 93/06950

A. CLASSIFICATION OF SUBJECT MATTER

IPC5: A61N 1/378

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC5: A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

DIALOG (CLAIMS; WPI, MEDLINE); ORBIT (USPM)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US, A, 4323075 (LANGER), 6 April 1982 (06.04.82), column 2, line 3 - line 27; column 2, line 51 - line 65, figure 2, abstract --	1,3,5-9
A	US, A, 4134408 (BROWNLEE ET AL), 16 January 1979 (16.01.79), column 1, line 62 - column 2, line 5; column 4, line 43 - column 5, line 45, figure 2, abstract --	1,3,5-9
A	US, A, 4345604 (RENIRIE), 24 August 1982 (24.08.82), column 4, line 9 - line 47, figures 1, 2, abstract --	1,6,8,9

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Date of the actual completion of the international search

21 October 1993

Date of mailing of the international search report

22. 11. 93

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 93/06950

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US, A, 4416282 (SAULSON ET AL), 22 November 1983 (22.11.83), column 3, line 54 - line 61, figure 6, abstract ----- --	1,3,4

SP 7345

INTERNATIONAL SEARCH REPORT
Information on patent family members

01/10/93

International application No.

PCT/US 93/06950

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US-A- 4323075	06/04/82	NONE	
US-A- 4134408	16/01/79	NONE	
US-A- 4345604	24/08/82	DE-A,B- 2702517	04/08/77
		GB-A- 1575975	01/10/80
		NL-A- 7700597	26/07/77
		US-A- 4031899	28/06/77
		US-A- 4120306	17/10/78
US-A- 4416282	22/11/83	NONE	

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